WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB393 trade name][*]

Rifapentine 300 mg tablets

[TB393 trade name], manufactured at Lupin Limited, Aurangabad, Maharashtra State, India, was included in the WHO list of prequalified medicinal products for the treatment and prophylaxis of tuberculosis (TB) on 15 July 2024.

[TB393 trade name] is indicated for treatment and prophylaxis of tuberculosis (TB). Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients of [TB393 trade name] rifapentine.

The efficacy and safety of rifapentine are well established based on extensive clinical experience in the treatment and prophylaxis of TB.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of rifapentine in TB, the team of assessors advised that [TB393 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB393 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB393 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	15 July 2024	listed
Pharmaceutical quality	23 June 2024	MR
Bioequivalence	08 July 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	31 March 2023	MR
FPP	28 January 2022	MR
GCP/GLP (re-)inspection	26 January 2024	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
NA: not applicable, not available
PQ: prequalification

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.